## **Complete Summary**

#### **GUIDELINE TITLE**

Prevention and control of meningococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP).

#### BIBLIOGRAPHIC SOURCE(S)

Prevention and control of meningococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2000 Jun 30;49(RR-7):1-10. [69 references]

### **COMPLETE SUMMARY CONTENT**

SCOPE

**CATEGORIES** 

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

IDENTIFYING INFORMATION AND AVAILABILITY

#### **SCOPE**

DISEASE/CONDITION(S)

Meningococcal disease

**GUIDELINE CATEGORY** 

Prevention

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses Health Care Providers Nurses
Physician Assistants
Physicians
Public Health Departments

#### GUI DELI NE OBJECTI VE(S)

- To summarize and update an earlier published statement issued by the Advisory Committee on Immunization Practices (ACIP) concerning the control and prevention of meningococcal disease (MMWR Morb Mortal Wkly Rep 1997 Feb 14; 46[RR-05]:1–21)
- To provide updated recommendations regarding the use of meningococcal vaccine

#### TARGET POPULATION

Individuals and populations at increased risk for meningococcal disease:

- For preexposure protection with meningococcal vaccine: Risk groups include persons with certain medical conditions (such as deficiencies in the terminal common complementary pathway and anatomic or functional asplenia); college freshmen who live in dormitories; travelers to endemic or epidemic areas; and persons with occupational risk (laboratory personnel exposed to Neisseria meningitidis).
- For postexposure chemoprophylaxis: Close contacts of infected persons, including household members, day care center contacts, and anyone directly exposed to the patient's oral secretions.

#### INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Preexposure protection against meningococcal infection with the quadrivalent meningococcal polysaccharide A, C, Y, W-135 vaccine (Menomune(R) A,C,Y,W-135; each dose consists of 50 micrograms of the four purified bacterial capsular polysaccharides), the formulation currently available in the United States.
- 2. Postexposure chemoprophylaxis with rifampin, ciprofloxacin, or ceftriaxone.
- 3. Prospects for improved vaccines using serogroup A, C, Y, and W-135 meningococcal polysaccharides chemically conjugated to protein carriers.

#### MAJOR OUTCOMES CONSIDERED

- Vaccine immunogenicity and efficacy
- Duration of vaccine-induced clinical protection
- Incidence of adverse effects associated with vaccine administration

#### METHODOLOGY

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

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Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

#### RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- 1. Preexposure Protection with the Meningococcal Vaccine
  - Routine vaccination of civilians. Current Advisory Committee on Immunization Practices (ACIP) guidelines (CDC, 1997) suggest that routine vaccination of civilians with the quadrivalent meningococcal polysaccharide vaccine is not recommended because of its relative ineffectiveness in children aged <2 years (the age group with the highest risk for sporadic disease) and because of its relatively short duration of protection.
  - Vaccination during outbreaks. The vaccine is recommended for use in control of serogroup C meningococcal outbreaks. An outbreak is defined by the occurrence of three or more confirmed or probable cases of serogroup C meningococcal disease during a period of ≤3 months, with a resulting primary attack rate of at least 10 cases per 100,000 population. For calculation of this threshold, population-based rates are used and not age-specific attack rates, as have been calculated for college students. These recommendations are based on experience with serogroup C meningococcal outbreaks, but these principles may be applicable to outbreaks caused by the other vaccine-preventable meningococcal serogroups, including Y, W-135, and A.
  - College freshmen. College freshmen, particularly those living in dormitories or residence halls, are at modestly increased risk for meningococcal disease compared with persons the same age who are not attending college. Therefore, ACIP has developed recommendations that address educating students and their parents about the risk for disease and about the vaccine so they can make individualized, informed decisions regarding vaccination. Please refer to the National Guideline Clearinghouse (NGC) summary for the guideline titled "Meningococcal Disease and College Students (2000)" for vaccination recommendations specific for college students.
  - High-risk groups. Routine vaccination with the quadrivalent vaccine is recommended for certain high-risk groups, including persons who have terminal complement component deficiencies and those who have anatomic or functional asplenia. Research, industrial, and clinical laboratory personnel who are exposed routinely to Neisseria meningitidis in solutions that may be aerosolized also should be considered for vaccination (CDC, 1997).
  - Travelers and U.S. citizens in endemic areas. Vaccination with the quadrivalent vaccine may benefit travelers to and U.S. citizens residing in countries in which N. meningitidis is hyperendemic or epidemic, particularly if contact with the local population will be prolonged. Epidemics of meningococcal disease are recurrent in that part of sub-Saharan Africa known as the "meningitis belt," which extends from Senegal in the West to Ethiopia in the East (Reido, Plikaytis, & Broome, 1995). Epidemics in the meningitis belt usually occur during the dry season (i.e., from December to June); thus, vaccination is recommended for travelers visiting this region during that time. Information concerning geographic areas for which vaccination is recommended can be obtained from international health clinics for travelers, state health departments, and CDC (contact information is given in the guideline document).
  - Revaccination. Revaccination may be indicated for persons at high risk for infection (e.g., persons residing in areas in which disease is epidemic), particularly for children who were first vaccinated when

they were <4 years of age; such children should be considered for revaccination after 2–3 years if they remain at high risk. Although the need for revaccination of older children and adults has not been determined, antibody levels rapidly decline over 2–3 years, and if indications still exist for vaccination, revaccination may be considered 3–5 years after receipt of the initial dose (CDC, 1997).

Precautions and Contraindications. See the "Potential Harms" field for adverse reactions to polysaccharide meningococcal vaccine.
 <u>Pregnancy</u>. Studies of vaccination during pregnancy have not documented adverse effects among either pregnant women or newborns (de Andrade Carvalho et al., 1977; Leston et al., 1998). Based on data from studies involving the use of meningococcal vaccines and other polysaccharide vaccines during pregnancy, altering meningococcal vaccination recommendations during pregnancy is unnecessary.

#### 2. Antimicrobial Chemoprophylaxis

• Chemoprophylaxis of close contacts of infected persons. In the United States, the primary means for prevention of sporadic meningococcal disease is antimicrobial chemoprophylaxis of close contacts of infected persons (see Table 1 in the guideline document for dosage and administration schedule). Close contacts include a) household members, b) day care center contacts, and c) anyone directly exposed to the patient's oral secretions (e.g., through kissing, mouth-to-mouth resuscitation, endotracheal intubation, or endotracheal tube management). The attack rate for household contacts exposed to patients who have sporadic meningococcal disease is an estimated four cases per 1,000 persons exposed, which is 500-800 times greater than for the total population (The meningococcal disease surveillance group, 1976).

Because the rate of secondary disease for close contacts is highest during the first few days after onset of disease in the index patient, antimicrobial chemoprophylaxis should be administered as soon as possible (ideally within 24 hours after identification of the index patient). Conversely, chemoprophylaxis administered >14 days after onset of illness in the index patient is probably of limited or no value. Oropharyngeal or nasopharyngeal cultures are not helpful in determining the need for chemoprophylaxis and may unnecessarily delay institution of this preventive measure.

• Eradication of nasopharyngeal carriage of N. meningitidis. Rifampin, ciprofloxacin, and ceftriaxone are all 90%-95% effective in reducing nasopharyngeal carriage of N. meningitidis and are all acceptable alternatives for chemoprophylaxis (Broome, 1986; Gaunt & Lambert, 1988; Dworzack et al., 1988; Schwartz et al., 1988). Systemic antimicrobial therapy of meningococcal disease with agents other than ceftriaxone or other third-generation cephalosporins may not reliably eradicate nasopharyngeal carriage of N. meningitidis. If other agents have been used for treatment, the index patient should receive chemoprophylactic antibiotics for eradication of nasopharyngeal carriage before being discharged from the hospital (Abramson & Spika, 1985).

- Special patient groups.
  - Rifampin. Rifampin is not recommended for pregnant women because the drug is teratogenic in laboratory animals. Because the reliability of oral contraceptives may be affected by rifampin therapy, alternative contraceptive measures should be considered while rifampin is being administered.
  - Ciprofloxacin. Ciproflaxacin is not generally recommended for persons less than 18 years of age or for pregnant or lactating women because the drug causes cartilage damage in immature laboratory animals.

#### CLINICAL ALGORITHM(S)

None provided

#### EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

Current Advisory Committee on Immunization Practices (ACIP) guidelines, in addition to an epidemiological study, formed the basis of the recommendations for use of the meningococcal vaccine.

Epidemiological and efficacy studies support the recommendations for antimicrobial chemoprophylaxis agents.

#### BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

## Meningococcal vaccine:

• Vaccine immunogenicity and efficacy: The immunogenicity and clinical efficacy of the serogroups A and C meningococcal vaccines have been well established. The serogroup A polysaccharide induces antibody in some children as young as 3 months of age, although a response comparable with that occurring in adults is not achieved until age 4-5 years. The serogroup C component is poorly immunogenic in recipients ages < 18-24 months. The serogroups A and C vaccines have demonstrated estimated clinical efficacies of > 85% in school-aged children and adults and are useful in controlling outbreaks. Serogroups Y and W-135 polysacharides are safe and immunogenic in adults and in children aged > 2 years; although clinical

- protection has not been documented, vaccination with these polysaccharides induces bactericidal antibody.
- Duration of protection: Vaccine-induced clinical protection likely persists in school-aged children and adults for at least 3 years, the efficacy of the group A vaccine in children aged < 5 years may decrease markedly within this period. In one study, efficacy declined from > 90% to < 10% 3 years after vaccination among children who were aged < 4 years when vaccinated; efficacy was 67% among children who were ≥ 4 years of age at vaccination.

#### Antimicrobial chemoprophylaxis:

• Rifampin, ciprofloxacin, and ceftriaxone are all 90-95% effective in reducing nasopharyngeal carriage of N. meningitidis.

#### POTENTIAL HARMS

#### Meningococcal vaccine

- Mild adverse reactions. Adverse reactions to polysaccharide meningococcal vaccines are generally mild; the most frequent reaction is pain and redness at the injection site, lasting for 1–2 days. Estimates of the incidence of such local reactions have varied, ranging from 4% to 56%. Transient fever occurred in up to 5% of vaccinees in some studies and occurs more commonly in infants.
- Severe adverse reactions. Severe reactions to polysaccharide meningococcal vaccine are uncommon. Most studies report the rate of systemic allergic reactions (e.g., urticaria, wheezing, and rash) as 0.0–0.1 per 100,000 vaccine doses. Anaphylaxis has been documented in < 0.1 per 100,000 vaccine doses. Neurological reactions (e.g., seizures, anesthesias, paresthesias, diplopia, optic neuritis) are also observed infrequently.
- Adverse events temporally associated with vaccination: The Vaccine Adverse Events Reporting System (VAERS) is a passive surveillance system that detects adverse events that are temporally (but not necessarily causally) associated with vaccination, including adverse events that occur in military personnel. In the United States from July 1990 through October 1999, a total of 264 adverse events (and no deaths) were reported. Of these adverse events, 226 were categorized as "less serious," with fever, headache, dizziness, and injection-site reactions most commonly reported. Thirty-eight serious adverse events (i.e., those that require hospitalization, are lifethreatening, or result in permanent disability) that were temporally associated with vaccination were reported. Serious injection site reactions were reported in eight patients and allergic reactions in three patients. Four cases of Guillain-Barré Syndrome were reported in adults 7-16 days after receiving multiple vaccinations simultaneously, and one case of Guillain-Barré Syndrome was reported in a 9-year-old boy 32 days after receiving meningococcal vaccine alone. An additional seven patients reported serious nervous system abnormalities (e.g., convulsions, paresthesias, diplopia, and optic neuritis); all of these patients received multiple vaccinations simultaneously, making assessment of the role of meningococcal vaccine difficult. Of the 15 miscellaneous adverse events, only three occurred after meningococcal vaccine was administered alone. The minimal number of serious adverse events coupled with the substantial amount of vaccine

distributed (> 4 million doses) indicate that the vaccine can be considered safe.

#### IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Staying Healthy

IOM DOMAIN

Effectiveness

#### IDENTIFYING INFORMATION AND AVAILABILITY

#### BIBLIOGRAPHIC SOURCE(S)

Prevention and control of meningococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2000 Jun 30;49(RR-7):1-10. [69 references]

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Jun 30

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

**United States Government** 

**GUI DELI NE COMMITTEE** 

Advisory Committee on Immunization Practices (ACIP)

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Advisory Committee on Immunization Practices (ACIP) Membership List, August 1999: John F. Modlin, M.D. (Chairman); Dixie E. Snider, Jr., M.D., M.P.H. (Executive Secretary); Dennis A. Brooks, M.D., M.P.H.; Richard D. Clover, M.D.; David W. Fleming, M.D.; Fernando A. Guerra, M.D.; Charles M. Helms, M.D., Ph.D.; David R. Johnson, M.D., M.P.H.; Chinh T. Le, M.D.; Paul A. Offit, M.D.; Margaret B. Rennels, M.D.; Lucy S. Tompkins, M.D., Ph.D.; Bonnie M. Word, M.D.

Meningococcal Vaccine and College Students Working Group: Robert Ball, M.D., M.P.H., M.Sc.; M. Miles Braun, M.D., M.P.H.; David W. Fleming, M.D. (Chairman); Pierce Gardner, M.D.; Samuel L. Katz, M.D.; Chinh T. Le, M.D.; Georges Peter, M.D.; Fred Rubin; William Schaffner, M.D.; David H. Trump, M.D., M.P.H.; James C. Turner, M.D.; Martin I. Meltzer, Ph.D.; Bradley A. Perkins, M.D.; Nancy E. Rosenstein, M.D.; R. Douglas Scott, II, Ph.D.

Centers for Disease Control and Prevention (CDC) Staff Members: Nancy E. Rosenstein, M.D. and Bradley A. Perkins, M.D.

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUI DELI NE STATUS**

This is the current release of the guideline.

This report summarizes and updates an earlier published statement issued by the Advisory Committee on Immunization Practices concerning the control and prevention of meningococcal disease (MMWR 1997:46[No. RR-5]:1--21) and provides updated recommendations regarding the use of meningococcal vaccine.

An update is not in progress at this time.

#### GUIDELINE AVAILABILITY

Electronic copies: An HTML Text version is available from the <u>Centers for Disease</u> <u>Control and Prevention (CDC) Web site.</u>

Also available (in Portable Document Format [PDF]) from the <u>Centers for Disease Control and Prevention (CDC) Web site</u>.

Print copies: Available from the Centers for Disease and Control Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

#### AVAILABILITY OF COMPANION DOCUMENTS

None available

#### PATIENT RESOURCES

None available

## NGC STATUS

This summary was completed by ECRI on August 28, 2000. The information was verified by the guideline developer as of November 17, 2000.

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